



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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New York District

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUEST**

Michael Wu, President  
Mandarin Soy Sauce, Inc.  
4 Sands Station Road  
Middletown, NY 10940

July 31, 2001

File No. NYK 2001-101

Dear Mr. Wu:

The U.S. Food and Drug Administration (FDA) has reviewed the labels for the Wan Ja Shan "LITE" Soy Sauce, 10 fl. oz. The labels were collected by an FDA Investigator during an inspection of your firm between August 29 and September 1, 2000.

The Lite Soy Sauce is misbranded within the meaning of section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the label bears the nutrient content claim "Lite," but the product fails to qualify for making the claim. The sodium content for the Lite Soy Sauce is reduced by 20% from the reference amount customarily consumed (RACC) when compared to the reference food. However, in order to qualify for making a "Lite" claim, the sodium content for the Lite Soy Sauce must be reduced by at least 50% from the RACC when compared to the reference food [Title 21 Code of Federal Regulations (21 CFR) §101.56(c)(1)(i)].

The Lite Soy Sauce is misbranded within the meaning of section 403(a)(1) of the Act in that the statements "Recommended for those who should restrict their salt intake" and "Wan Ja Shan's Lite soy sauce has approximately 30% less salt than our regular soy sauce" are misleading for a food containing 730 mg. per serving. The percent difference between 730 mg. and 910 mg. is actually about 20%, not the declared 30% on the label. Further, we question whether the statement "Wan Ja Shan's Lite soy sauce has approximately 30% less salt than our regular soy sauce" is a truthful statement because salt is generally composed of 39% sodium by weight.

The Lite Soy Sauce is misbranded within the meaning of section 403(r)(1)(A) of the Act in that the label bears the nutrient content claim "Less Sodium," but the product fails to qualify for making the claim. The sodium content for the Lite Soy Sauce is reduced by 20% from the RACC when compared to the reference food. However, in order to qualify for making a "Less Sodium" claim, the sodium content for the Lite Soy Sauce must be reduced by at least 25% from the RACC when compared to the reference food [21 CFR §101.61(b)(6)].

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Mandarin Soy Sauce, Inc.  
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A check of supermarkets as recently as July 31, 2001 indicates this product continues to be offered for sale with the objectionable label claims as described above.

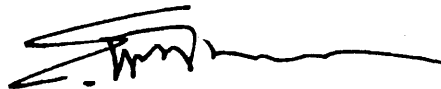
The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies concerning your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes and regulations enforced by FDA.

You should take prompt measures to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Richard T. Trainor, Compliance Officer, U.S. Food and Drug Administration, 300 Hamilton Ave., White Plains, New York 10601. If you have any questions concerning the violations noted, then please contact Mr. Trainor at 914-682-6166 x 34.

Sincerely,

A handwritten signature in black ink, appearing to read 'Edward W. Thomas', with a long horizontal flourish extending to the right.

Edward W. Thomas  
Acting District Director